AUG 16 2000

K001106

Summary of Safety and Effectiveness

Creative Plastic **MasterSite Luer Activated Needleless IV Connector**

1.0 GENERAL INFORMATION

1.1 **Intended Use:** The MasterSite™ Needleless Luer Activated IV Connector is an accessory to administration sets to allow access devices to be connected to a patient's catheter or other patient luer lock devices without the need of a needle for the administration of fluids. The connector is single patient use only.

1.2 Trade Name: MasterSite™ Needleless Activated IV Connector

1.3 Common Name: Needleless Connector

1.4 Classification Name: Set, administration, intravascular

1.5 Classification Panel: General Hospital and Personal Use Devices

1.6 Product Code: FPA

1.7 Statement of Equivalence

1.7.1 The MasterSite Connector is substantially equivalent to (1) Baxter InterLink (K922558 and K925126) and (2) ICU Medical CLAVE Connector (K915571 and K970855).

2.0 DESCRIPTIONS OF DESIGN

2.1 The MasterSite Connector is provided sterile and non-pyrogenic. Each device is package individually and delivered in a shelf pack.

2.2 The device has a rotating female luer and a stationary male luer.

2.2.1 The Connector is activated by attaching to its female luer another luer device. The action of rotating the female threaded luer of the Connector moves the device from the closed position to the open position. The rotation causes the eccentric components (the female threaded luer and the stationary seal) to move into position.

2.3 The MasterSite Connector fluid path materials are in conformance with ISO 10993 Part 1.

3.0 OPERATIONAL SPECIFICATIONS

3.1 The MasterSite Connector is an accessory to administration sets and syringes intended to allow access devices to be connected to a patient's catheter or patient device without the need of a needle for the administration of fluids.

3.2 The MasterSite Connector is in the closed position as long as there is no device attached to the female luer connector.

3.3 When the healthcare professional (or other properly trained individuals) is ready to attach a device to the patient, the act of pressing and turning the luer lock device being attached while holding the MasterSite Connector opens the fluid path of the connector and allows fluid to flow.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 for fluid path components.

4.2 The ***MasterSite Connector*** is categorized as follows:

4.2.1 Device Category: External Communicating Device.

4.2.2 Body Contact: Blood Path Indirect

4.2.3 Contact Duration: Prolonged (24 hours to 30 days).

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility and Drug Stability

5.1.1 There are no specific drugs referenced in the labeling for the ***MasterSite Connector***. There are no drugs included in the ***MasterSite Connector***.

6.0 LABELS AND LABELING

6.1 The Directions for Use labeling:

6.1.1 Provides comprehensive directions for preparation and use.

6.1.2 Contains warning information.

6.1.3 Contains the prescription statement required under 801.109 (b)(1).

6.1.4 Includes product specifications.

6.2 Packaging labels

6.2.1 Contains the prescription statement required under 801.109(b)(1).

7.0 STANDARDS

7.1 There are currently no standards established for IV connectors.

8.0 STERILIZATION AND PYROGEN INFORMATION

8.1 The method of sterilization is radiation

8.1.1 Sterilization validation methodology for radiation sterilization is by ANSI/AAMI/ISO 11137:1994 and EN EN552.

8.2 The ***MasterSite Needleless IV Connector*** is labeled non-pyrogenic.

8.2.1 Pyrogenicity will be determined by using either USP 23 LAL testing or Rabbit pyrogen test.

9.0 PERFORMANCE TESTS

9.1 Functional testing

9.1.1 Testing was conducted to demonstrate that the functional characteristics of the ***MasterSite Connector.***

Test	Results
Pressure test (100 psi)	Pass
Reuse (100 open/closes at 50 and 100 psi)	Pass
Backflow test	Pass
Flow rate 5 ml/hr	Pass
Flow rate 100 ml/hr	Pass
Flow rate 1000 ml/hr	Pass

10.0 COMPARISON TO LEGALLY MARKETED DEVICES

10.1 The MasterSiteConnector is substantially equivalent to the Baxter InterLink (K922558 and K925126) and ICU Medical CLAVE Connector (K915571 and K970855).

10.2 Device Descriptions - Comparisons

Characteristic Compared	***MasterSite Connector***	Baxter InterLink K922558 and K925126	ICU Clave K915571 and K970855
Product Labeling	single use; contents of unopened, undamaged package are: sterile and nonpyrogenic	sterile, nonpyrogenic	sterile, nonpyrogenic fluid path in unopened undamaged package
Intended Use	an accessory to administration sets to allow access devices to be connected to a patient's catheter or other patient luer lock devices without the need of a needle for the administration of fluids	used with a vascular access device for fluid administration and blood sampling; the luer access injection site can be connected to male luer adapters (e.g., syringes or sets) to allow needleless access to the vascular path	as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.
Design	rotating two piece adapter; mechanical closure when luer lock device not attached; needleless priming volume 0.2ml	male luer lock adapter activated by the insertion of a non metallic cannula through resealable surface; needleless	a silicone seal which is depressed, with insertion of a male luer, below the openings of an internal plastic conduit, permitting fluid flow
Materials	polycarbonate body and rotating luer; silicone seal	Unknown	internal conduit - polycarbonate; silicone seal-silicone rubber; ring-polypropylene
Pressure tolerance	50 psi	Not stated	Not stated
Safety	No backflow	Not stated	Not stated

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2000

Creative Plastic Technology
C/O Mr. Robert J. Bard
Attorney at Law
Law Offices of Robert J. Bard
24312 Armada Drive
Dana Point, California 92629

Re: K001106
Trade Name: MasterSite Needleless Luer Activated IV Connector, Model MS 1000
Regulatory Class: II
Product Code: FPA
Dated: July 6, 2000
Received: July 10, 2000

Dear Mr. Bard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001106

510(k) Number (if known): _____

Device Name: *MasterSite™ Needleless Luer Activated I.V. Connector*

Indications for Use:

The ***MasterSite™ Needleless Luer Activated I.V. Connector*** is an accessory to an administration set or syringe to allow access devices to be connected to a patient's catheter or other patient luer devices without the need of a needle for the administration of fluids.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001106